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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/632,929	08/04/2003	David Wallach	WALLACH10D	4943

1444 7590 02/08/2007

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EXAMINER	
GAMBEL, PHILLIP	
ART UNIT	**PAPER NUMBER**
1644	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
31 DAYS	02/08/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/632,929	WALLACH ET AL.	
	Examiner	Art Unit	
	Phillip Gambel	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 November 2006*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-5* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-5* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. As indicated previously,
applicant's election of Group I and the species autoimmune diseases in the Reply To Restriction Requirement, filed on 7/31/06, was acknowledged.

Applicant's assertions that a reference identical to one group would not render the other group prima facie obvious is acknowledged.

However, the examiner was not in agreement with these assertions in the absence of a more complete explanation by applicant. For example, a common reference (e.g. the structure of human TBP-II) in combination with other references as well as other possibilities may provide for the obviousness of different Groups of products and processes.

Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Applicant's election of the species rheumatoid arthritis in the Response to Election of Species, filed 2/15/06, is acknowledged.

2. However, upon a closer inspection of the claims, the examiner realized that the claim 1 is drawn to an immunoassay for detecting TBP-II, while claim 2 is drawn to a diagnostic assay to measure anti-TBP-II antibodies (not TBP-II itself).

Therefore, the previous Restrictions are vacated to set forth the following Restriction to clarify the Groups and species.

The examiner apologizes for this inconvenience to applicant in this matter.

However, claims 1 and 2 have been placed in different Groups for the reasons set forth herein.

Claims 1-5 are pending.

3. In the interest of compact prosecution after an initial review of the instant application and the priority applications, the following is noted.

The filing date of the instant claims is deemed to be the filing date of priority application USSN 08/477,347, filed 6/7/95.

It is noted that priority applications USSNs 07/930,443 and 07/524,263 were not available to the examiner at this time.
Therefore, the examiner could not determine whether the instant claims have priority to said applications.

While there appears some disclosure of some assays and some diseases in the priority applications,
it is noted that the other priority applications recited for benefit of priority prior to the filing of USSN 08/477,347, filed 6/7/95, do not appear to provide sufficient support under 35 USC 112, first paragraph, for the current "immunoassay and diagnostic assays" as currently recited (e.g., "measuring the interaction", "measuring the level of antibodies to TBP-II endogenously produced in sera of patients in several disorders" and do not appear to provide sufficient written description for assay either rheumatoid arthritis or SLE as a disorder for such assays.

If applicant desires priority prior to 6/7/95, applicant is invited to point out and provide documentary support for the priority of the instant claims.

Applicant is reminded that such priority for the instant limitations requires written description and enablement under 35 U.S.C. 112, first paragraph

4. Also, in the interest of compact prosecution, applicant is invited to amend claim 2 to recite structural properties (e.g., SEQ ID NOS.) for TBP-II to avoid being subject to rejections under 35 USC 112, first paragraph, enablement and written description.

5. Restriction to one of the following inventions is required under 35 U.S.C. § 121:

I. Claim 1, drawn to an immunoassay to detect TBP-II, classified in Class 435, subclass 7.1.

II. Claim 2, drawn to a diagnostic assay to detect anti-TBP-II antibodies, classified in Class 435, subclass 7.1.

III. Claim 3, drawn to methods of purifying, classified in Class 530, subclass 413.

IV. Claims 4-5, drawn to methods of producing peptides, classified in Class 435, subclass 69.6

6. Inventions I/II/III/IV are different methods of use. These inventions require different ingredients, process steps and endpoints. With respect to Groups I-II, it is noted that Group I is directed to assays that detect TBP-II, while Group II is directed to detecting the level of antibodies to TBP-II endogenously produced in sera of patients in several disorders. Therefore, Groups I and II are directed to assay or detecting two distinct molecules. Antibodies and proteins do not share a common structure to a common utility. Therefore they are patentably distinct.

7. Because these inventions are distinct for the reasons given above and the search required for any group from Groups I-IV is not required for any other group from Groups I-IV and Groups I-IV have acquired a separate status in the art as shown by their different classification and divergent subject matter, restriction for examination purposes as indicated is proper.

8. If Group II is elected,
then this application contains claims directed to the following patentably distinct species of the claimed invention II: wherein applicant is required to elect a particular disorder, provided that the instant application provides sufficient written description for different disorders.
It is noted page 21 of the instant specification appears to provide for certain diseases (e.g. rheumatoid arthritis or SLE).

However as noted previously, the written support for diagnosing "several disorders" and what those disorders to be diagnosed are is not readily apparent.

These species are distinct because the disorders would differ in etiologies and therapeutic endpoints.

Applicant is required under 35 U.S.C. § 121 to elect a single disclosed species of a pathological condition for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 2 is generic.

9. Applicant is advised that a response to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 C.F.R. § 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. M.P.E.P. § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. § 103 of the other invention.

10. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

11. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phillip Gambel whose telephone number is (571) 272-0844. The examiner can normally be reached Monday through Thursday from 7:30 am to 6:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841.

The fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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February 5, 2007